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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,959	04/04/2006	Paul D. Rennert	13751-055US1 A184 US	5124

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
03/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/540,959	RENNERT, PAUL D.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *45,47,55,56,58 and 59*.
   Claim(s) withdrawn from consideration: *44 and 57*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 12/23/08

13. ☐ Other: I.

/Maher M. Haddad/
Primary Examiner, Art Unit 1644

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 45, 47, 55-56 and 58-59 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammatory bowel disease with KIM-1-Ig fusion protein, does not reasonably provide enablement for a method of treating an autoimmune disease/immunological disorder in a subject comprising administering an antagonist antibody or antigen-binding fragment thereof that binds to KIM-1, wherein the disorder/disease is inflammatory bowel disease in claims 45, 47, 55-56 and 58-59. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in the previous Office Action mailed 4/21/08 and 11/19/08.

Applicant's arguments, filed 2/19/09, have been fully considered, but have not been found convincing, however it remains the Examiner's position that the skilled in the art would not expect that the antagonist anti-KIM-1 antibodies would treat IBD or other immunological disorders recited in the claims. The exemplification in the specification is drawn to inhibition of IFN-g production in vitro (Example 11) by KIM-1-Ig and anti-KIM-1 antibodies and in vivo treatment with KIM-1-Ig fusion protein conferred significant protection to mice, as indicated by the improvement in the weight score and fewer blood present in the fecal pellets (Example 12 and fig. 14&15). While the specification uses "active immunization" with KIM-1-Ig to block IFN-g production, the claims requires a "passive immunization" with an antibody to KIM-1. Given the teachings of Xiao et al, and Umetsu et al (of record), and importantly the teachings of Encinas et al (IDS reference AFF) that administration of anti-TIM-1 (KIM-1) antibody to mice (in vivo) has on effect on TH1 cytokine IFN-g production (see abstract). Moreover, Hoo et al (Clinical and experimental Immunology (2006), 145(1):123-129) teaches that administering anti-TIM-1 antibodies to a mice enhances interferon (IFN)-g production (see abstract in particular). Administering such antibodies to a subject with an autoimmune disease, the antibodies either would not treat (Encinas et al) or would exacerbate (Hoo et al) the autoimmune disease including IBD in a subject. Applicant's disclosure does not appear to have provided the skilled artisan with sufficient guidance and support as how to extrapolate data obtained from these assays to the development of effective in vivo human therapeutic methods, commensurate in scope with the claimed invention.

While Applicant admits that the examples are describe the use of a polypeptide containing the extracelluar doamin of KIM-1 protein, whereas the claimed methods are directed to the use of an anti-KIM-1 protein. However, Applicant provides no evidence to counter the in vivo teachings of both Xiao and Hoo references.

In the absence of evidence to the contrary, both Xiao and Hoo references are the controlling art for the enablement issue because it is the closest art to the invention. The in vivo data of Xiao and Hoo references are the controlling data in the instant case because the claims are drawn to the use of the anti-KIM-1 antibody in vivo not in vitro as argued.